IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* ELLSWORTH ASSOCIATES, LLP, Plaintiff-Relator, v. CVS HEALTH CORPORATION, *et al.*, Defendants.	Case No.: 2:19-cv-02553-JMY

RELATOR'S SUR-REPLY BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

Defendants wholly fail to explain why Relator's allegations are insufficient to state a plausible False Claims Act ("FCA") violation. Defendants incredibly suggest that because Congress permitted plan sponsors to prefer brand-name drugs over generics on their formulary, Congress gave a green light to Defendants' fraudulent conduct in implementing that preference. But Congress did not authorize Defendants to mislead beneficiaries about the availability and cost of generic drugs, deny formulary exceptions to block access to certain generic drugs, instruct pharmacies not to stock certain generic drugs, or conceal any of that conduct, particularly where Defendants' fraudulent scheme ultimately resulted in higher costs to the Government. All of that conduct plausibly states a claim for fraud on the Government within the meaning of the FCA. Indeed, if Defendants' conduct was actually designed to generate cost-savings, as Defendants contend, their fraud would have been completely unnecessary.

Perhaps realizing that their motion to dismiss did not target Relator's actual allegations, Defendants' reply brief raises a host of new grounds for dismissal. This Court need not even consider those belated arguments. But even if this Court does, it should decline to dismiss the Second Amended Complaint ("SAC"). Construing the SAC in Relator's favor, and drawing all reasonable inferences, Relator has plausibly alleged that, had the Government known of Defendants' fraudulent efforts to obstruct competition and deceive beneficiaries into choosing a Part D plan in which their costs would be higher (because they were then denied access to generic drugs, also making the Government's reimbursement costs higher), the Government would not have approved Defendants' Part D plans or their requests for reimbursement under those plans. Defendants' newfound contentions that their alleged fraudulent conduct was neither material nor knowing rings hollow and, in any event, is inconsistent with the SAC's allegations.

ARGUMENT

I. ELLSWORTH HAS ADEQUATELY ALLEGED VIOLATIONS OF THE FALSE CLAIMS ACT.

A. Defendants Have Waived Any Argument That the Antitrust Allegations Are Insufficient.

Relators' Brief in Opposition to Defendants' Motion to Dismiss ("Opp.") explained that Defendants failed to dispute that their alleged conduct violated the antitrust laws. Opp. at 16-21. For example, Defendants' Brief in Support of their Motion to Dismiss ("Opening Brief") did not even mention the terms "antitrust," "Clayton Act," "Sherman Act," "exclusive deal," "rule of reason," "relevant market," or "anticompetitive." Defendants now seek to cure that failure. *See* Reply in Support of Defendants' Motion to Dismiss ("Reply") at 4-7. But it is well established that an argument first raised in a reply brief is waived. *Laborers' Int'l Union v. Foster Wheeler Corp.*, 26 F.3d 375, 398 (3d Cir. 1994); *accord In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II)*, 751 F.3d 150, 158 (3d Cir. 2014).

Defendants' suggestion that Relator is attempting to "recast" its FCA case as an antitrust case is nothing more than an effort to circumvent their waiver. The antitrust allegations were pled in the complaint, *see, e.g.*, SAC ¶¶ 8, 21, 55-59, 212-77, 353, such that Defendants were on notice of those claims when they filed their Motion to Dismiss. Defendants, therefore, may not save their challenge to those allegations for the reply brief in an attempt to have the last word. *See Smithkline Beecham PLC v. Teva Pharms. USA, Inc.*, Nos. 04–0215, 05–0536(NLH)(JS), 2007 WL 1827208, at *1 (D.N.J. June 22, 2007) ("Reply briefs are not the time to present new argument."); *accord United States v. Martin*, 454 F. Supp. 2d 278, 281 n.3 (E.D. Pa. 2006).

B. In Any Event, Defendants' Challenge to the Antitrust Allegations Lacks Merit.

Even if the Court were to consider Defendants' tardy antitrust arguments, the Ellsworth SAC adequately stated a claim that Defendants' conduct violated the antitrust laws by using their deceptive business practices to unreasonably stymie competition. Opp. at 17-18. Defendants argue (Reply at 18-19), without any authority, that the FCA cannot be used to punish anticompetitive conduct. But such an interpretation of the FCA is overly restrictive and inconsistent with the wide range of fraudulent conduct it covers – *i.e.,* "all types of fraud, without qualification, that might result in financial loss to the Government[.]" *U.S. ex rel. Drescher v. Highmark, Inc.*, 305 F. Supp. 2d 451, 457 (E.D. Pa. 2004) (citation omitted). This includes "each and every claim submitted under a contract . . . *originally obtained* . . . *in violation of any statute*." *Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1048 (9th Cir. 2012) (quoting S. Rep. No. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274); *see also U.S. ex rel. Marcus v. Hess,* 317 U.S. 537, 542-44 (1943) (bid rigging claims submitted under contract obtained in violation of federal requirement were false). Here, Relator has alleged that Defendants' fraudulent conduct barred the Government and SilverScript beneficiaries from accessing identical, less expensive generic drugs, thereby precluding competition in the SilverScript market for certain name-brand drugs, in violation of antitrust laws. *See, e.g.*, SAC ¶¶ 1, 3, 6, 254, 290-91, 321, 499.[1]

[1] The allegations here are similar to those in numerous cases where False Claims Act liability was premised on anticompetitive conduct. *See, e.g.*, *Marcus,* 317 U.S. 537 (bid rigging); *U.S. ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, 741 F.3d 390 (4th Cir. 2013) (price fixing); *U.S. ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, 608 F.3d 871 (D.C. Cir. 2010) (bid rigging); *United States v. CFW Constr. Co.*, 649 F. Supp. 616 (D.S.C. 1986) (bid rigging), *dismissed on other grounds,* 819 F.2d 1139 (4th Cir. 1987); *United States v. Beatrice Foods Co.*, 330 F. Supp. 577 (D. Utah 1971) (bid rigging); *see also Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787-88 (4th Cir. 1999) (observing that collusive bidding can form the basis of a False Claims Act case).

Defendants misleadingly cite (Reply at 5) *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 207 (3d Cir. 2005), for the proposition that Ellsworth must plead four elements to state a Sherman Act claim. *Gordon*, however, concerned what must be *proved* to survive a Rule 56 summary judgment motion, not what must be *pled* to survive a Rule 12(b)(6) motion. *Id.* On a motion to dismiss, Plaintiffs "need only state enough facts to 'raise a reasonable expectation that discovery will reveal evidence of illegal agreement,' even if the court believes such proof is improbable." *SigmaPharm, Inc. v. Mut. Pharm. Co.*, 772 F. Supp. 2d 660, 669 (E.D. Pa.) (quoting *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544, 562 (2007)), *aff'd* 454 F. App'x 64 (3d Cir. 2011).

Defendants further argue (Reply at 6) that the SAC fails to allege a relevant market. They are mistaken. A relevant product market "is defined as those 'commodities reasonably interchangeable by consumers for the same purposes.'" *Tunis Bros. Co. v. Ford Motor Co.*, 952 F.2d 715, 722 (3d Cir. 1991) (citations omitted). Here, the SAC clearly defines the relevant market as the SilverScript Part D plans whose beneficiaries in the United States were, from June 22, 2015 through today, denied access to cheaper generic drugs and were instead required to pay for fifteen more expensive, brand-name drugs. SAC ¶¶ 1-2, 5, 127-32 (discussion of generic drugs), 348-49. Thirteen of the brand-name drugs at issue had available so-called "authorized generics," which are identical to the brand-name, other than the assigned national drug code ("NDC").[2] Thus, the SAC alleges a relevant market in that the fifteen brand-name drugs at issue and their generics are alleged to be functionally interchangeable. To the extent Defendants wish to dispute the validity of that allegation, that is inappropriate at the motion to dismiss stage. *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2017 WL 4910673, *16 (E.D. Pa.

[2] SAC ¶¶ 133-39, 225-30, 345-47, 351-52, 402-05 (Invega authorized generic), 428-33 (Asacol HD authorized generic), 459-62 (Renvela authorized generic), 495-96 (Harvoni and Epclusa authorized generic), 618-20 (Ventolin HFA), 683 (Advair Discus).

Oct. 30, 2017); *see also Reazin v. Blue Cross & Blue Shield of Kan., Inc*., 899 F.2d 951, 975 (10th Cir. 1990) (noting that "[m]arket definition is a question of fact.").

Finally, Defendants suggest (Reply at 6-7) that Relator has not alleged an antitrust injury. This argument fails for three reasons. *First*, Relator is not required to plead an antitrust injury. *Bradburn Parent/Teacher Store, Inc. v. 3M (Minn. Mining & Mfg. Co.),* Civ. A. No. 02-7676, 2000 WL 34003597, at *2 (E.D. Pa. July 25, 2003) ("There are no special pleading requirements for an antitrust claim. Rather, '[n]otice pleading is all that is required[.]'"). In any event, because courts at the motion to dismiss stage "must accept as true the factual allegations in the complaint and all reasonable inferences that can be drawn from them," the existence of antitrust injury is not typically resolved through motions to dismiss. *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.,* 113 F.3d 405, 417 (3d Cir. 1997).

Second, the SAC alleges anticompetitive injury in that SilverScript beneficiaries were denied access to cheaper generic drugs, which depressed demand for these drugs in the SilverScript Part D market, resulting in higher costs for beneficiaries and the Government. SAC ¶¶ 214, 264-77. The SilverScript beneficiaries' and Government's injury "reflect[s] the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *W. Penn Allegheny Health Sys., Inc. v. UPMC,* 627 F.3d 85, 101 (3d Cir. 2010) (internal citations omitted).

Third, to prevail on their procompetitive affirmative defense (Reply at 7), Defendants must show that the SAC demonstrates "as a matter of law (1) nonpretextual, procompetitive justifications … for the allegedly anticompetitive actions …, and (2) that the procompetitive benefit of these actions outweigh their anticompetitive harm." *BRFHH Shreveport, LLC v. Willis Knighton Med. Ctr.*, 176 F. Supp. 3d 606, 623 (W.D. La. 2016). Defendants cannot satisfy that

standard at this stage because it would require facts beyond those alleged in the SAC. *Id.* at 623-25.

C. Relator Has Adequately Alleged False Certification Claims.

1. The SAC Adequately Alleges That Defendants Falsely Certified Their Compliance with State Mandatory Generic-Substitution Laws

a. Defendants' Falsehoods Were Material

Defendants challenge materiality (Reply at 9-10) solely on the ground that Relator has not adequately alleged that CMS would have refused to reimburse prescriptions that did not comply with state generic-substitution laws. That is simply not true. The SAC's allegations, taken together, reasonably permit an inference that CMS would have refused to reimburse prescriptions for brand-name drugs dispensed in violation of state generic-substitution laws, such that Defendants' noncompliance with those laws was material. Relator alleged that prescriptions that violate state generic substitution laws are not valid prescriptions, and that CMS will only reimburse for drugs dispensed pursuant to a "valid prescription." *See, e.g.*, SAC ¶¶ 22(h), 193-196, 326, 330 (CVS Health agreed to pay only "valid" claims).[3] Relator further alleged that Defendants' failure to require its network pharmacies to comply with the state generic substitution laws was not minor or insubstantial, but went to the "essence of the bargain," *Universal Health Srvs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 194, 196 & n.5 (2016), because it increased the amount of the Government's reimbursement. *See, e.g.*, SAC ¶¶ 206-09, 271 (Defendants knew that violation of the generic substitution laws would result in higher prices to Medicare), 326. Violations that increase the Government's costs are plainly material to its payment decision. *See, e.g., Ruckh v.*

[3] Defendants dispute (Reply at 9) that a prescription must comply with state generic-substitution laws to be "valid." At the pleadings stage, however, this Court must credit Relator's factual allegation to the contrary. *See, e.g.*, *U.S. ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 248 (3d Cir. 2016).

Salus Rehab., LLC, 963 F.3d 1089, 1105-06 (11th Cir. 2020) (upcoding and ramping were material as they affected the amount of reimbursement from Medicare); *U.S. ex rel. Foreman v. AECOM*, 19 F.4th 85, 117 (2d Cir. 2021) (labor billing and timesheet fraud were material because they led to substantial overpayments by the government), *cert. denied*, 142 S. Ct. 2679 (2022). Thus, the SAC adequately alleges that, if CMS had known that brand-name drugs were dispensed in violation of state generic-substitution laws, resulting in invalid prescriptions that cost the Government more, CMS would have refused to reimburse those claims. *See, e.g.*, SAC ¶¶ 24(a) (Government has paid false claims for "invalid Part D prescriptions that would not have been paid but for CVS Health's intentional, illegal, improper, and reckless business practices"); 24(c) (alleging Government entered into contracts with CVS based on false assertions of compliance with federal laws and regulations). Thus, Relator sufficiently alleged materiality. *See, e.g.*, *Winter ex rel. U.S. v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1122 (9th Cir. 2020) (materiality adequately pled where relator alleged that government would not have paid claims had it known of the alleged violation).

The conclusion that Defendants' noncompliance with state generic substitution laws was material is further underscored by Defendants' efforts to conceal that conduct. *See, e.g.*, Opp. at 48-49; SAC ¶ 21(g) (submitting materially false records in support of claims); *id.* ¶ 23 (CVS made false and misleading statements to avoid detection and conceal their conduct); *id.* ¶ 113 (SilverScript applied scheme selectively to reduce risk of CMS audit); *id.* ¶ 290 (CVS publicly supported competition among drug manufacturers); *id.* ¶ 296 (CVS represented to United States Senate that it encouraged use of generics); *id.* ¶ 308-09 (Defendants concealed that brand-name drugs would not be cost neutral to Medicare or beneficiaries); *id.* ¶ 548 (in denying formulary exception, SilverScript concealed that the generic was cheaper); *id.* ¶ 659-69 (CVS concealed from

beneficiary the right to request a generic). Courts have routinely recognized that efforts to cover up violations of payment conditions weigh in favor of materiality. *See, e.g.*, *U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018); *U.S. ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 544 (10th Cir. 2020); *U.S. ex rel. Armstrong v. Andover Subacute & Rehab Ctr. Servs. One, Inc.*, No. 12-03319-SDW-SCM, 2019 WL 4686963, at *6 (D.N.J. Sept. 26, 2019).

Defendants argue (Reply at 9-10) that the fact that the Government has taken no action to stop Part D plans from employing a brand-preference strategy precludes an inference that Defendants' noncompliance with state generic substitution laws is material. But again, Defendants confuse the fact that Medicare Part D generally permits providers to adopt formularies that prefer brand-name drugs, which Relator does not contest, with Defendants' alleged violation of state generic-substitution laws. In any event, absent evidence that the Government knew that Defendants were violating state generic-substitution laws, the Government's continued payment of Part D prescriptions does not bear on materiality. *See, e.g., Escobar*, 579 U.S. at 195 ("[I]f the Government pays a particular claim in full *despite its actual knowledge that certain requirements were violated*, that is very strong evidence that those requirements are not material.") (emphasis added). Defendants have not alleged that the Government knew that they were violating state generic-substitution laws. Indeed, as discussed above, Defendants attempted to conceal those violations through false records and false DAW codes.[4]

[4] In any event, Relator was not required to allege that the Government routinely denies reimbursement for prescriptions dispensed in violation of state generic-substitution laws to plead materiality. *U.S. ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 833-34 (6th Cir. 2018); *Escobar*, 579 U.S. at 194-95 (enumerated factors are non-exhaustive and not dispositive). Accordingly, the Court may not draw an adverse inference against Relator based on the lack of such allegations. *Prather*, 892 F.3d at 833-34; *U.S. ex rel. Wallace v. Exactech, Inc.*, No. 2:18-cv-01010-LSC, 2020 WL 4500493, *16 (N.D. Ala. Aug. 5, 2020).

Defendants' reliance on *U.S. ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 764 (3d Cir. 2017), is therefore misplaced. In that case, unlike here, it was undisputed at the merits stage that the Government was aware of the alleged misrepresentations and nevertheless continued to pay for those prescriptions. *Id.* Moreover, the misrepresentations in *Spay* were a "technical, formulaic way of preventing a computer program from denying legitimate claims for reimbursement." *Id.* at 765. Thus, unlike here, the alleged misrepresentations in *Spay* did not alter which prescriptions or the amounts the Government would have reimbursed.

Defendants argue (Reply at 9) that it is not plausible that CMS would have denied payment for brand-name, on-formulary drugs, because that would have resulted in Part D enrollees bearing the full cost of the generic drugs. But Defendants' argument relies on a fallacy. Because Defendants were required to approve formulary exceptions (through Tier 4 cost-sharing), Part D beneficiaries would *not* have borne the full cost of a generic. Opp. at 32; *see also* SAC ¶ 282. Indeed, Defendants' Call Center representatives informed beneficiaries that formulary exceptions requests, including for generics, would be covered at the highest cost share level (*e.g.*, Tier 4). SAC ¶¶ 378, 386, 406, 435, 438, 442, 466, 503, 506, 510, 516, 520, 631, 647, 650, 654. And CMS would undoubtedly reimburse a patient's request for the generic, which would be cheaper than the brand-name, even at Tier 4 cost-sharing.

b. Defendants Acted Knowingly

Defendants contend (Reply at 10) that, because their interpretation of the generic substitution laws was objectively reasonable within the meaning of *Safeco*, and no guidance warned them away from that interpretation, Relator failed to allege that Defendants knowingly violated the FCA. Defendants are wrong. As Relator explained (Opp. at 29), the Third Circuit has not issued binding precedent broadly applying *Safeco* to the FCA. In *U.S. ex rel. Streck v. Allergan, Inc.*, which is not precedential, the Third Circuit applied *Safeco*'s objective

reasonableness test only to the "reckless disregard" prong of the FCA's scienter requirement. 746 F. App'x 101, 106 (3d Cir. 2016) (unpublished). *Streck* explicitly distinguished "reckless disregard" from "deliberate ignorance," explaining that "[a]llegations of deliberate ignorance demonstrate conduct and knowledge *particularized to a given defendant*." *Id.* at 106 n.4 (emphasis added). *Streck*, therefore, did not conclude that Defendants' state of mind or subjective intent is always irrelevant to the FCA's scienter requirement, as Defendants contend (Reply at 12), such that a defendant's objectively reasonable interpretation of a regulation or statute precludes liability.

Other courts have similarly recognized that an objectively reasonable interpretation does not excuse a defendant's regulatory violation if there is evidence of a defendant's state of mind. *See, e.g.*, *U.S. ex rel. Gugenheim v. Meridian Senior Living, LLC*, 36 F.4th 173, 179-82 (4th Cir. 2022) (concluding that defendants were entitled to summary judgment only when defendants' interpretation of ambiguous regulation was objectively reasonable *and* relator "failed to marshal evidence from which a reasonable jury could find that Defendants acted with the requisite state of mind"); *U.S. ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155 (11th Cir. 2017) ("[S]cienter is not determined by the ambiguity of a regulation, and can exist even if a defendant's interpretation is reasonable."); *U.S. ex rel. Donegan v. Anesthesia Assocs. of Kan. City, P.C.*, 833 F.3d 874, 879-880 (8th Cir. 2016) (evidence that a defendant was warned away from an otherwise reasonable interpretation of a regulation shows scienter).[5] These cases reflect the purpose of the

[5] Defendants misleadingly suggest (Reply at 10) that the Government has advocated applying *Safeco* broadly to FCA claims such that the scienter requirement turns only on an objectively reasonable interpretation, but that is not correct. *See, e.g.*, *Donegan*, 833 F.3d at 879 (acknowledging United States' amicus brief that "protest[ed] that the district court 'adopted the sweeping rule that a defendant's reasonable interpretation of an ambiguous regulation precludes FCA liability, regardless of the defendant's state of mind'"). DOJ's Statement of Interest in *Streck* (attached as Exhibit A) makes this clear: "The [FCA's] deliberate ignorance language makes clear that it is a defendant's own knowledge and actions that are the subject of the scienter inquiry, and that Congress did not intend for a defendant to ignore its obligations, bury its head in the sand, and

objectively reasonable standard, which is to prevent the FCA from "reach[ing] an innocent, good-faith mistake about the meaning of an applicable rule or regulation." *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287-88 (D.C. Cir. 2015). Where there is evidence of a defendant's state of mind (including that he or she has been warned away from a particular interpretation of a regulation), however, a regulatory violation cannot be presumed to be "an innocent, good-faith mistake," and a defendant should not escape liability merely because he is able to offer an objectively reasonable interpretation *post hoc*. *See, e.g.*, *United States v. Supervalu Inc.*, 9 F.4th 455, 473 (7th Cir. 2021) (Hamilton, C.J., dissenting) (criticizing majority for overreading *Safeco* to "create[] a safe harbor for deliberate or reckless fraudsters whose lawyers can concoct a *post hoc* legal rationale that can pass a laugh test"), *petition for cert. filed*, No. 21-1326 (Apr. 1, 2022); *accord U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 357 (4th Cir.) (Wynn, C.J., dissenting), *vacated on reh'g en banc*, 49 F.4th 873 (4th Cir. 2022).

Here, the SAC includes allegations that permit an inference that Defendants knew that they were violating the generic substitution laws and/or that they were deliberately ignorant of those laws, even if their interpretation of those laws was objectively reasonable. *See, e.g.*, Opp. at 48-49; SAC ¶ 113 (SilverScript selectively applied scheme to reduce risk of CMS audit), *id.* ¶ 116 (Ms. Miller was instructed to monitor for grievances related to generic block and to notify management), *id.* ¶ 216 (CVS Health Executive Committee knew of risk posed by scheme, but determined that benefit outweighed the risk); *id.* ¶ 503 (Executive Committee approved the scheme despite concerns from senior management that it was "highly unethical"); *see also id.* ¶¶ 271, 290, 293, 296, 308-09, 320, 529, 548, 626-27, 659-69. Thus, even if *Safeco*'s objectively reasonable

escape liability by relying on arguments that are later raised during litigation." Ex. A. at 2. In addition, DOJ's recent amicus briefs in *Sheldon* and *Island Industries* (attached as Exhibits B and C) both advocated against extending *Safeco* to the FCA. Ex. B at 24-25 and Ex. C at 22-23.

standard applies to the FCA, Relator has adequately alleged scienter here because Relator does not rely solely on Defendants' alleged violation of state generic-substitution laws.

But, even if Defendants were correct that evidence as to their state of mind is wholly irrelevant under *Safeco*, Relator explained (Opp. at 30) that Defendants' interpretation of state generic-substitution laws was *not* objectively reasonable. Defendants have offered no explanation as to how dispensing a more expensive, brand-name drug in a state that unambiguously requires a generic drug to be substituted whenever the generic is cheaper could be an objectively reasonable interpretation of those state generic-substitution laws, even if Defendants are generally permitted to prefer brand-name drugs on their formularies. Again, Defendants conflate preferring brand-name drugs on a formulary, which is permissible, with dispensing brand-name drugs in all circumstances, including when prohibited by state generic-substitution laws. Such an interpretation is objectively *un*reasonable.

c. The SAC Plausibly Alleges Defendants Submitted False Claims by Using False DAW Codes

Defendants' incorrect DAW code submissions were not merely "imprecise"—they were fraudulent. Opp. at 31-34. This is because Defendants' top-down scheme—to ensure that only more expensive, brand-name medications were dispensed in violation of generic substitution laws—put pharmacists in the untenable position of choosing a proper DAW code when none of the available codes applied. Thus, Defendants knew incorrect DAW codes would be submitted.

Defendants claim (Reply at 13) that a DAW code is not material because it has no bearing on CMS's payment decision; rather the only information in the PDE record that is relevant to CMS is whether the drug is on formulary. This argument is unavailing. PDE records are "clearly claims for payment." *U.S. ex rel. Spay v. CVS Caremark* Corp., 913 F. Supp. 2d 125, 168 (E.D. Pa. 2012); *see also U.S. ex rel. Buth v. Pharmerica Corp.*, No. 09-C-0720, 2014 WL 4355342, at *2 (E.D.

Wis. Sept. 3, 2014). "Courts have long held that pharmacies' PDEs, if they are alleged to contain false or inaccurate data, are false claims for purposes of the FCA." *U.S. ex rel. Mohajer v. Omnicare, Inc.*, 525 F. Supp. 3d 447, 452 (S.D.N.Y. 2021) (internal citations omitted). That is because PDE data is used to ensure correct payment, as well as to validate claims, monitor quality, and make year-end risk corridor calculations. SAC ¶ 151; *see also Buth*, 2014 WL 4355342, at *2. The DAW codes are thus a critical part of the submitted claim, particularly when the incorrect codes result in higher payments by CMS for more expensive brand-name drugs. Defendants have provided no authority to the contrary.

Defendants rely (Reply at 13) on *Spay,* 875 F.3d 746, to support their argument that DAW codes are not material. As explained above, however, *Spay*, is not persuasive authority here because it was decided on summary judgment and involved an extensive factual record that established the dummy prescriber codes were only a technical violation and did not affect the Government's payment decision. No similar record or facts exist here.

Rather, "in considering a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court generally considers only the allegations in the complaint, accepting them as true, and the defendant bears the burden of showing that the plaintiff has not stated a claim." *U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 299 n.4 (3d Cir. 2016). In analyzing whether Relator's allegations are actionable, the Court analyzes whether Defendants' noncompliance was "substantial," such that it would have the tendency to affect the Government's payment decision. *Ruckh*, 963 F.3d at 1105 (misrepresentations causing the government to pay more for Medicare reimbursement were material). Here, the SAC adequately alleges Congress intended Part D plans to provide quality drugs at affordable prices (SAC ¶¶ 2, 8, 55), relying on marketplace competition to ensure that drug prices are fairly negotiated to make these often

lifesaving medications more affordable (*id.* ¶¶ 61-64, 143-50, 350, 352), including providing access to cheaper generic drugs (*id.* ¶¶ 129, 277, 296, 538, 544-47, 608, 614), which goes directly to the quality of healthcare Part D beneficiaries received (*id.* ¶ 277). Moreover, Defendants' scheme increased the beneficiaries' cost for these more expensive brand-name drugs (*id.* ¶ 491), making them unaffordable for many beneficiaries (*id.* ¶¶ 19, 352, 544, 588, 681), and resulting in higher costs for the Government (*id.* ¶ 271).[6] These allegations are sufficient to plead materiality. *See supra* at pp. 6-7.

Defendants misconstrue (Reply at 13-14) the case law addressing the materiality of DAW codes. Despite its outcome, the reasoning of *U.S. ex rel. Fox Rx, Inc. v. Omnicare, Inc.,* 38 F. Supp. 3d 398, 411-12 (S.D.N.Y. 2014), squarely supports the materiality of DAW codes. *See also United States v. TEVA Pharms. USA, Inc.*, No. 13 CIV. 3702 (CM), 2016 WL 750720, *25 (S.D.N.Y. Feb. 22, 2016) (PDEs that contain false or inaccurate data are false claims).

Defendants further contend (Reply at 14) that Relator has failed to allege that Defendants *knowingly* used incorrect DAW codes. As Relator explained (Opp. at 34), however, Defendants' use of incorrect DAW codes was not an innocent mistake, but an attempt to cover up the fact that Defendants were avoiding filling prescriptions with generic drugs, even when required to do so by state law. Defendants argue (Reply at 14) that such a cover-up is simply not plausible because "CVS Pharmacy is not the only pharmacy to fill prescriptions for SilverScript enrollees." But the fact that other pharmacies may have also used incorrect DAW codes does not undermine Relator's alleged scheme of vertical integration amongst CVS entities, which required CVS pharmacies to use incorrect DAW codes to obscure their violation of the state generic-substitution laws. As

[6] Defendants' argument (Reply at 13) that only on-formulary drugs could be "legitimately reimbursed" is palpably false. As Relator explained (Opp. at 45), non-formulary drugs approved under a formulary exception are "covered" under Medicare Part D.

explained above, evidence of Defendants' efforts to cover up their violations is relevant to show scienter, even if Defendants' view that correct DAW codes were not necessary for dispensing prescriptions was objectively reasonable. *See supra* pp. 10-11.

d. The SAC Plausibly Alleges the "Adverse Effects" of Denying Formulary Exceptions Caused False Claims to Be Submitted

Recognizing that they had ignored the "adverse effects" prong of the formulary exception rule, Defendants now insist (Reply at 15-16) that entitlement to a formulary exception is based only on "clinical" concerns, and may not be based on a drug's cost. Defendants are wrong. Indeed, Defendants' new position is at odds with the very purpose of Part D, which mandates implementation of cost management tools in formulary management.[7] In order to "achieve appropriate, safe, and cost effective therapy," formulary management includes both clinical and pharmacoeconomic considerations.[8] Read in context, therefore, the formulary exception rule itself, which specifically includes consideration of whether the formulary drug "is likely to . . . *adversely affect* . . . *patient compliance*," 42 C.F.R. § 423.578(b)(5)(ii)(A), makes clear that formulary exceptions may be granted for both clinical and financial considerations.

Defendants' exclusive focus on clinical concerns cannot be reconciled with the rule's plain language or CMS guidance and is therefore objectively unreasonable. *See U.S. ex rel. Sorensen v. Outreach Diagnostic Clinic LLP*, No. H-12-00480, 2020 WL 1272609, at *2 (S.D. Tex. Mar. 16,

[7] CMS, Medicare Part D Prescription Drug Manual, Chapter 18, "Part D Enrollee Grievances, Coverage Determinations, and Appeals," Section 30.1.2, Rev. Nov. 30, 2005 ("[f]ormulary use includes the application of cost utilization tools"), available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/PartDManualAppeals_113005.pdf.

[8] *Id.*, Chapter 6, "Part D Drugs and Formulary Requirements," Section 30.1.5, Rev. Jan. 15, 2016 ("Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe, and cost effective drug therapy."), available at https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.

2020) (rejecting argument of ambiguity where "interpretation misses a plain reading of the code and creates ambiguity out of clarity"); *see also U.S. ex rel. Banigan v. Organon USA Inc.*, No. 07-12153-RWZ, 2016 WL 10704126, at *4 (D. Mass. Aug. 23, 2016) (defendant's interpretation may be objectively unreasonable if it ignores available, relevant information).

Defendants' reliance on *In re Case of A.S. Cmty. CCRx Claim for Prescription Drug Benefits (Part D)*, No. M-13-791, 2013 WL 7872029 (HHS Medicare Appeals Council Apr. 15, 2013), is entirely misplaced. *A.S.* involved a request for a statutorily **excluded** brand-name drug, Caverject, to treat a condition not covered by Medicare: erectile dysfunction.[9] Thus, because Caverject is not a Covered Part D Drug, there is no right to a formulary exception.[10] *See* 42 C.F.R. § 423.578(e). The beneficiary nonetheless requested a formulary exception based solely on cost, and the request was correctly denied because Caverject is not covered under Medicare Part D. That is a far cry from the case at bar, where all fifteen drugs are Covered Part D Drugs for which there should have been a right to a formulary exception.

e. Defendants Concede Their Fraudulent Marketing Caused the Submission of False Claims

Defendants causal link argument (Reply at 16-17) ignores altogether the detailed allegations in the SAC that Defendants knew their marketing claims were materially misleading. Opp. at 42-43. Defendants go further in their Reply and argue (Reply at 16-17) that deceiving SilverScript beneficiaries could not have been "integral" to false claims submitted to the Government because the causation chain is "long and tenuous." But this argument is irrelevant to a fraudulent inducement claim. Opp. at 41. Here, as in *Hendow*, "the precise logistical details of

[9] Effective January 1, 2007, P.L. No. 109-91, section 103, amended section 1860D-2(e)(2)(A) of the Act to exclude from the statutory definition of a Part D drug "a drug when used for the treatment of sexual or erectile dysfunction."

[10] *See* HHS OIG, Review of Erectile Dysfunction Drugs in the Medicare Part D Program, A-07-10-03143 (March 2011), available at https://www.oig.hhs.gov/oas/reports/region7/71003143.pdf.

how the claim is made—with respect to timing, for instance, or the number of stages involved—are immaterial: '[i]f a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork.'" *U.S. ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1174 (9th Cir. 2006) (alteration in original) (citation omitted). It thus has no bearing in establishing the causal chain that beneficiaries themselves do not submit claims to the Government. The fact remains that, as alleged in the SAC, it was integral to the submission of false claims that beneficiaries were induced by the fraudulent representations to enroll in a SilverScript plan. SAC ¶¶ 221, 225, 249, 259; *see* Opp. at 42-43.

For the first time, Defendants argue (Reply at 17) that the SAC does not allege they expressly or impliedly certified compliance with the CMS Part D plan marketing regulations. This argument ignores that the SAC alleges Defendants' express certifications to comply with Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse (Opp. at 8, 12, 33, 49-50) and their implied certifications that they would comply with laws and regulations governing communications with Part D beneficiaries (Opp. at 22, 44-46). *See, e.g.*, 42 C.F.R. § 423.2262(a)(1) ("Part D sponsors may not . . . [p]rovide information that is inaccurate or misleading.").

Defendants quibble (Reply at 17-18) with whether their marketing claims that beneficiaries would "save money" and that the SilverScript plan would "cover the cost" of their expensive drugs are false, arguing it is generally true that beneficiaries save money on a SilverScript plan. However, even Defendants admit (Reply at 18) that, but for their scheme, "[m]aybe" it is true that beneficiaries would have saved "more money" if they had been allowed access to the cheaper generics. Defendants' equivocation illustrates this is exactly the kind of marketing claim which should be left to the factfinder to "analyze the message conveyed in full context." *U.S. ex rel.*

Knisely v. Cintas Corp., 298 F.R.D. 229, 242-43 (E.D. Pa. 2014). "When the challenged [representation] is implicitly rather than explicitly false, its tendency to . . . mislead[ ], confus[e] or deceiv[e] should be tested by public reaction." *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 943 (3d Cir. 1993) (citations omitted). But that determination is on the merits and cannot be made at the pleadings stage. *Knisley*, 298 F.R.D. at 243.

Defendants conjure up a new argument (Reply at 18) that their general marketing statements were mere "puffery," and therefore not actionable. This is incorrect. The hallmarks of puffery are that they are "[s]ubjective claims . . . which cannot be proven either true or false." *Time Warner Cable, Inc. v. DIRECTV, Inc.,* 497 F.3d 144, 159 (2d Cir. 2007) (citation omitted). But claims that may be tested by the factfinder are actionable. Here Defendants' claims that they would *always* act on behalf of beneficiaries ("every prescription is more than a mere transaction; each is a *commitment* to demonstrate our expertise and *sole focus* on delivering Part coverage that helps participants on their path to better health") or that they would "save you money" and would "cover the cost" of their expensive drugs, or that SilverScript plans would "protect your health savings," should be tested by the jury in the context of Defendants' overall scheme to determine whether beneficiaries would have been misled by these claims. Likewise, Call Center statements telling beneficiaries that cheaper generics were not available on the SilverScript formulary "because of market conditions outside [CVS Health's] control" would be susceptible to inquiry as to the timing and details of specific agreements CVS Caremark had entered into with the brand-name manufacturers blocking access to specific generics. A jury should decide whether beneficiaries reasonably relied on these statements. *See, e.g.*, *In re Petrobras Sec. Litig.*, 116 F. Supp. 3d 368, 381 (S.D.N.Y. 2015) (finding that statements, although when "viewed in isolation, m[ight] be

[considered] mere puffery," were actionable because they were "made repeatedly in an effort to reassure the investing public," and thus "a reasonable investor could rely on them").

With regard to Defendants' argument (Reply at 18) that some statements were not misleading and therefore are not actionable, this too is wrong. Half-truths may be actionable even if they are literally true but still misleading "through context and manner of presentation." *See, e.g.*, *Kleinman v. Elan Corp.,* 706 F.3d 145, 152 (2d Cir. 2013) (citation omitted). When Defendants told beneficiaries that the non-formulary drugs would only be available at the "highest cost-sharing level," even though in fact the actual cost would still be lower than the more expensive brand-name drugs (Opp. at 45), this half-truth, even if technically true, was deceptive, particularly because of Defendants' violation of their legal duty to provide beneficiaries accurate price differentials for "covered drugs."[11] Opp. at 45-46; SAC ¶¶ 146-50. These allegations more than adequately plead actionable half-truths. *See, e.g.*, *Gagnon v. Alkermes PLC*, 368 F. Supp. 3d 750, 769 (S.D.N.Y. 2019) (Local 731 pled an actionable half-truth in violation of the securities laws); *see also In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 240 (2d Cir. 2016).

Although some of Defendants' marketing claims, when viewed in isolation, may appear to be too vague to be actionable (Reply at 17-18), when viewed in the context of Defendants' carefully calibrated, multifaceted scheme to block vulnerable beneficiaries attempting to get access to cheaper generic drugs, the Defendants' half-truths are actionable. *See, e.g.*, *In re Henry Schein, Inc. Sec. Litig.*, No. 18-CV-01428 (MKB), 2019 WL 8638851, *12 (E.D.N.Y. Sept. 27, 2019) (in

[11] In light of Relator's explanation (Opp. at 45-46) that Defendants were obligated to provide beneficiaries with price differential information about "covered" drugs (including for non-formulary drugs), Defendants have apparently abandoned their deeply flawed argument (Br. at 43) that they had no obligation to inform beneficiaries of the cost differentials for non-formulary drugs.

context, Schein's half-truths failed to disclose to a reasonable investor that it did not operate in a competitive market and instead had colluded with competitors to fix prices).

In disputing (Reply at 19) that SilverScript's marketing statements are material, Defendants again misstate *Escobar*'s materiality standard. As explained above, *see supra* p. 8 n.4, Relator is not required to allege that the Government "consistently refused to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement," *Escobar*, 579 U.S. at 195. Rather, materiality turns on whether the marketing statements would have had a tendency to influence the Government's payment decision. *See* Opp. at 27 (quoting 31 U.S.C. § 3729(b)(4)). As Relator explained (Opp. at 41-43), Defendants' marketing misrepresentations fraudulently induced Part D beneficiaries to join SilverScript's plan, resulting in false claims. Thus, because the misrepresentations were material to Part D beneficiaries' decisions, they were necessarily material to the Government's decision to reimburse beneficiaries' claims under that plan.

Defendants likewise argue (Reply at 19) that Relator failed to allege that the non-disclosure of cost differentials to Part D beneficiaries was done knowingly. But that is solely because Defendants dismiss as irrelevant Relator's allegations that Defendants were purposely deceiving Part D beneficiaries about the relative costs of brand-name drugs and generics. As discussed above, however, even if Defendants' interpretation of the relevant statutes and regulations were objectively reasonable, that does not make evidence of Defendants' state of mind irrelevant. *See supra* pp. 10-11.

f. The SAC Plausibly Alleges Defendants Falsely Certified Compliance with Federal Laws and Regulations

Defendants raise a new argument (Reply at 19), positing they have met the Part D compliance requirements simply by having a compliance program, no matter how insufficient that

compliance program may be. But CMS requires that Part D Sponsors "must establish and implement an *effective* system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the sponsor's . . . compliance with CMS requirements and the overall *effectiveness* of the compliance program."[12] The word "effective" "typically describes things—such as policies, treatments, arguments, and techniques—that do what they are intended to do."[13] The SAC adequately alleges that Defendants lacked an effective compliance program because an effective system would have identified the fact that SilverScript was not granting formulary exceptions when beneficiaries were specifically inquired and asked for these rights. SAC ¶¶ 22, 212-17, 275; *see also* Opp. at 48, 50.

g. The SAC Plausibly Alleges False Claims for Violations of the Firewall and FTC Consent Order

Having ignored Relator's reverse false claims allegations in their Opening Brief, Defendants take a new tack, arguing (Reply at 21-22) that Ellsworth has failed to allege a contractual *obligation* to pay the stipulated fine for breach of the FTC Consent Order. Defendants cite *Sturgeon* for the proposition that there is no "obligation" to pay a penalty when it is "contingent on the government's prosecutorial discretion." Reply at 21 (citing *Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d 246, 279 (E.D. Pa. 2020)). Defendants improperly conflate the government's discretion *to enforce* an obligation to pay with the government's discretion *to impose* such an

[12] Element VI: Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks Prescription Drug Benefit Manual Chapter 9 - Compliance Program Guidelines and Medicare Managed Care Manual, 50.6 – Element VI: Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks (emphasis added)[12]; *see also* SAC ¶¶ 77-87.

[13] *See* "Effective," Merriam-Webster, available at https://www.merriam-webster.com/dictionary/effective.

obligation in the first instance. *Sturgeon* addressed only the latter and turned on the language of the defendant's corporate integrity agreement, which provided that a violation "*may* lead to the imposition of . . . monetary penalties." 438 F. Supp. at 279 (alteration in original) (footnote omitted). Thus, *Sturgeon* is limited to instances where the underlying agreement with the Government makes clear that the imposition of a duty to pay penalties is discretionary.[14] *Id.* The penalties the Defendants agreed to with the FTC, however, were mandatory.

Defendants assert (Reply at 21) it is "absurd" to argue that a reverse false claim "flows from the failure to voluntarily pay penalties to the FTC." Defendants' argument is a strawman, and a poorly disguised one at that. The FTC's letter explains that penalties are mandatory for violations of the consent order: "to the extent that [CVS Health] and/or any of its subsidiaries . . . violates the terms of the Commission's final order … it *would* be liable for civil monetary penalties." SAC ¶ 262. Moreover, the FTC letter explains that Defendants' liability for violating the FTC orders is "pursuant to Section 5(l) of the FTC Act." SAC ¶ 262. Section 5(l) of the FTC Act provides that any party violating an order of the Commission "*shall* forfeit and pay to the United States a civil penalty of not more than $10,000 for each violation." 15 U.S.C. § 45(l) (emphasis added).[15]

Defendants' argument of last resort (Reply at 21) is that the Firewall Agreement and Consent Order are "irrelevant." But Defendants' *ipse dixit* does not make their obligations vanish. The SAC adequately alleges Defendants' ongoing violation of their obligation to "not misrepresent, or assist others in misrepresenting, in any manner, expressly or by implication, the

[14] *Sturgeon* is at odds with another district court decision in this Circuit, *U.S. ex rel. Boise v. Cephalon, Inc.*, No. 08–287, 2015 WL 4461793 (E.D. Pa. July 21, 2015), which held that violation of a corporate integrity agreement created an "obligation," even where the agreement specified that "failure to comply . . . *may* lead to the imposition of" fines. *Id.* at *4 (emphasis added).

[15] The use of the term "shall" in 15 U.S.C. § 45(l) plainly makes the obligation to pay mandatory.

price or cost of Medicare Part D drugs" (SAC ¶¶ 17, 259-63), which triggered an "established duty" to pay the fines under Section 5(l). Opp. at 51-54.

2. The SAC Adequately Alleges Conspiracy Claims

Defendants now argue (Reply at 22-23) that the SAC must allege an agreement expressing specific intent to violate the FCA; foreseeability of an FCA violation is not enough. Defendants' argument, however, misstates the legal standard. This Circuit has rejected the pleading standard applied in *Ibanez*, on which Defendants rely. *Compare Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156-57 (3d Cir. 2014) (plaintiff need only provide particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted), *with U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017) (requiring relators to provide specific examples of false claims to survive a Rule 12(b)(6) motion). Here Relator has plainly satisfied the *Foglia* standard by providing detailed allegations of the scheme, along with numerous representative false claims,[16] and by alleging actions taken in furtherance of the conspiracy that Defendants knew could foreseeably result in false claims being submitted to the Government. Opp. at 54-57.[17]

3. The SAC Is Not Barred by Public Disclosure

Defendants argue that the public disclosure bar applies because Relator purportedly admitted that there were public disclosures revealing "defendants' alleged brand-preference scheme, violations of state generic-substitution laws, and submissions of incorrect DAW codes."

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[16] SAC Exs. 9, 10, 11, 12, 13, 16, 18, 20, 22, 25, 26, 32, 33, 36, 38, 40, 41, 42, 43, 46, 47, 50, 51, 53, 54, 56, 59, 60, 62, 64, 65, 70, 76, 77.

[17] For this same reason, Defendants err in relying on *U.S. ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 121 (W.D. Pa. 2006), which pre-dated *Foglia*'s rejection of the more stringent Rule 9(b) standard. "'[A]llegations of the conspiracy need only satisfy the notice pleading standards of Rule 8.'" *United States v. Spivack*, No. CV 22-343, 2022 WL 4091669 (E.D. Pa. Sept. 6, 2022) (slip opinion) (citations omitted).

Reply at 23 (citing Opp. at 58). Defendants grossly misread Relator's Opposition. Although Relator observed that "*Defendants contend* that [CMS materials, news articles, two civil cases, and a Senate Finance Committee hearing] publicly revealed SilverScript's preference for brand-name drugs over generic drugs on its formulary, that such preference could result in higher prices for both Part D beneficiaries and the Government, and that Defendants allegedly violated state mandatory generic-substitution laws through the use of incorrect DAW codes," Relator explained that "*none of these public disclosures revealed 'substantially the same allegations' as Relator alleges here*." Opp. at 58 (emphases added). Relator then detailed why these public disclosures did not reveal the specific fraud alleged by Relator. Opp. at 58-60.

In response, Defendants fail to identify any public disclosures concerning the specific fraud alleged. Instead, Defendants simply rehash their argument (Reply at 23-24) that Relator's specific allegations of fraud do not violate the FCA. But that argument fails to meet Defendants' burden to show that the public disclosure bar applies.

Defendants further argue (Reply at 24) that, even if the public disclosure bar applies, Relator—a corporate entity—cannot qualify as an original source. The only authority Defendants cite in support of their novel argument that "individual," as used in the FCA, should exclude corporate entities, however, is *Clinton v. City of New York*, 524 U.S. 417, 428 & n.13 (1998). But in *Clinton*, the Supreme Court held that, in light of the Line Item Veto Act's structure and purpose, "individual" should "be construed as synonymous with the word 'person,'" which includes corporate entities. *Id.* at 428 (citing 1 U.S.C. § 1). The Eighth Circuit, following that same approach, concluded that "individual," in the context of the FCA, should have the same meaning as "person," and therefore rejected the argument that a corporate entity cannot be an original source. *Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1048 n.12

(8th Cir. 2002). Defendants' assertion that the Eighth Circuit's conclusion was "unreasoned" is belied its analysis. *Id.* (explaining that the original source exception should not be limited to natural persons because "[n]either the 1986 Amendments Act nor review of its background or legislative history suggests that Congress meant to exclude suits on the basis of whether the relator was a natural person, corporation, or association").

Finally, Defendants err in arguing (Reply at 25) that the Relator has failed to allege that its knowledge materially adds to the publicly disclosed allegations. Defendants suggest that Relator's knowledge is limited to a handful of paragraphs in the complaint. Reply at 25 (citing SAC ¶¶ 33-36, 116-18). Those paragraphs, however, simply describe how the allegations underlying the *entire* complaint derive from Ms. Miller's personal knowledge and experience. Ms. Miller's knowledge materially adds to the alleged public disclosures by describing the who, what, when, where, and how of Defendants' fraudulent scheme. *See* Opp. at 63-64. Defendants fail to grapple with these facts or offer any argument as to why they do not materially add to the purported public disclosures. This Court, therefore, should conclude that the public disclosure bar is inapplicable.[18]

CONCLUSION

For the foregoing reasons, this Court should deny Defendants' motion to dismiss Relator's complaint.

[18] Although Defendants' Opening Brief argued that CVS Health and CVS Pharmacy are improper defendants (Br. at 14-15), they have apparently abandoned that argument by failing to respond to Relator's Opposition (Opp. at 64-67). *Rosengrant v. Transcon. Gas Pipe Line Co.*, No. 4:20-CV-01555, 2020 WL 7260997, *3 n. 29 (M.D. Pa. Dec. 10, 2020).

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CERTIFICATE OF SERVICE

I certify that on December 1, 2022, this document was filed electronically, that it is available for viewing and downloading from the ECF system, and that all counsel of record will be served by the ECF system.

/s/ W. Scott Simmer